

SIMPLICITY REORDER NUMBERS

1002757 S Simplicity Mask w/ Standard Headgear
 1002759 M Simplicity Mask w/ Standard Headgear
 1002764 Standard Headgear

1018138 S Simplicity Mask w/ Deluxe Softcap Headgear
 1018158 M Simplicity Mask w/ Deluxe Softcap Headgear
 1006416 Deluxe Softcap Headgear

Replacement Parts

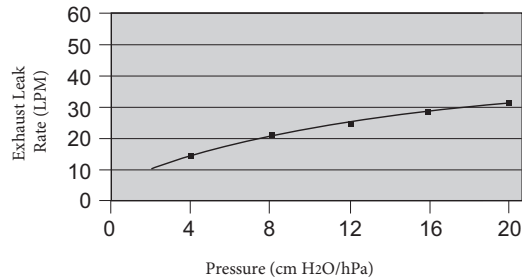
1003658 Simplicity Mask Cushion, Small, 1 each
 1003657 Simplicity Mask Cushion, Small, 5 pack
 1003659 Simplicity Mask Cushion, Medium, 1 each
 1003656 Simplicity Mask Cushion, Medium, 5 pack
 1004209 Faceplate Tubing Assembly

Visit www.respironics.com for a complete list of products and reorder numbers, or contact Customer Service at 1-800-345-6443 to obtain a product catalog (#1027825).

DISPOSAL

Dispose of damaged or broken parts and/or devices in accordance with local regulations.

Pressure vs. Leak Rate



Deadspace Volume

Small - 29.9 cc
 Medium - 38.5 cc

Pressure Drop (cm H₂O/hPa)

	50 LPM	100 LPM
Small	0.6	2.4
Medium	0.8	2.6



RESPIRONICS®
 1001 Murry Ridge Lane
 Murrysville, Pennsylvania
 15668-8550 USA

Storage Temperature -20° C to 60° C
 Relative Humidity up to 95%, non-condensing

Covered by one or more of the following patents:
 Des 448,473; Des 464,133; Des 464,428; and Des 493,523.
 Other patents pending.

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 JW 02/07/06

Simplicity™



NASAL MASK INSTRUCTIONS

MULTI-PATIENT USE REUSABLE LATEX FREE

INTENDED USE

The Respironics® Simplicity™ Nasal Mask is intended to provide an interface for adult patients when used with CPAP or bi-level therapy. The mask contains an exhalation port that provides a continuous leak path in the patient circuit. This mask does not require the use of a separate exhalation device.

CAUTION!

US federal law restricts this device to sale by or on the order of a physician.

SYMBOLS The following symbol is used on the mask.

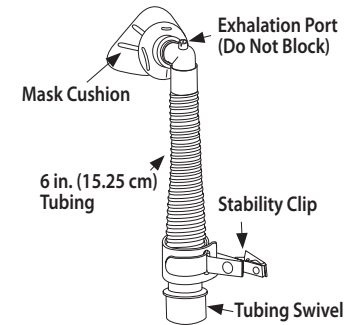


General Warning or Caution. Consult accompanying documents for detailed information.

WARNINGS

- This CPAP mask should be used only with CPAP systems recommended by your physician or respiratory therapist. A mask should not be used unless the CPAP system is turned on and operating properly. The vent hole or holes associated with the mask should never be blocked. Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP systems.
- At low CPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection and the leak rate. This warning applies to most CPAP or bi-level systems.
- If oxygen is used with the CPAP or bi-level system, the oxygen flow must be turned off when the system is not in operation. Explanation of Warning: When the CPAP or bi-level system is not in operation and the oxygen flow is left on, oxygen delivered in the ventilator tubing may accumulate within the CPAP or bi-level system enclosure. Oxygen accumulated in the CPAP or bi-level system will create a risk of fire. This warning applies to most CPAP or bi-level systems.
- Oxygen accelerates fires. Keep the CPAP or bi-level system and oxygen container away from heat, open flames, any oil substance, or other sources of ignition. Do not smoke in the area near the device or the oxygen container.
- Some users may experience skin redness. If this occurs, consult your healthcare professional.

SIMPLICITY MASK



STEP-BY-STEP USAGE INSTRUCTIONS

STANDARD HEADGEAR

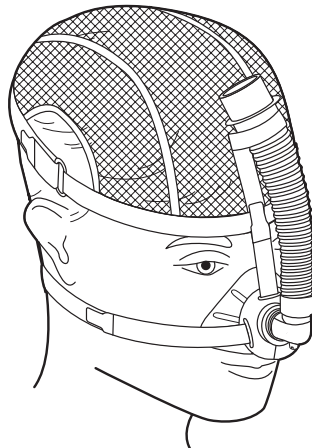
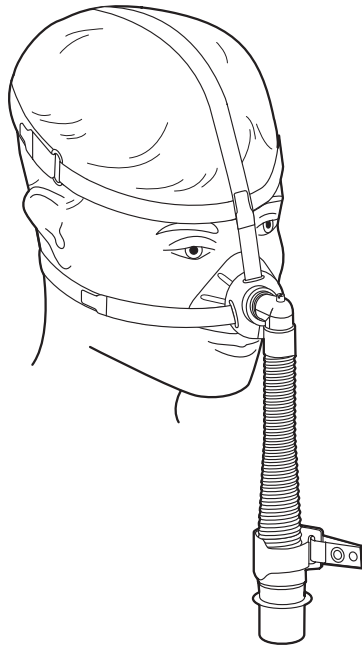
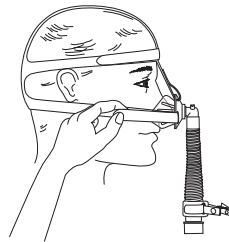
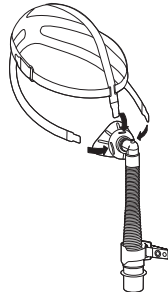
Step 1 Unhook the standard headgear's tabs and thread them through the slots in the mask. The arrow printed on the back of the headgear should be pointing upward. Fasten the tabs onto the straps for the largest size possible.

Step 2 Hold the mask in place on the tip of your nose, pressing comfortably against your face, and slide the headgear over your head. Adjust the straps to bring the cushion close to your face. Adjust the center strap so that the cushion sits comfortably over your nose.

Step 3 Connect the circuit tubing to the mask swivel. Turn the CPAP or bi-level system on. Optional: Attach the stability clip to the headgear strap.

Step 4 Lie down and breathe normally through your nose, keeping your lips closed. Unhook the straps and gradually tighten them until the mask has minimal leaks and fits comfortably. Adjust the top straps first, making sure that they are above your ears. Adjust the bottom straps, making sure the headgear securely fits the back of your head. Readjust the strap tension if leaks occur as your position changes. **NOTE: Do not** overtighten the straps. Overtightening can cause or worsen leaks.

NOTE: The tubing can be worn upward (over the head) or downward as desired using either the Standard or the Softcap Headgear as illustrated below.



DELUXE SOFTCAP HEADGEAR

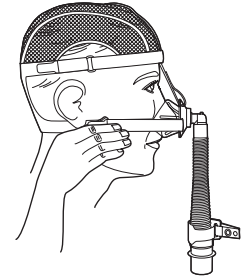
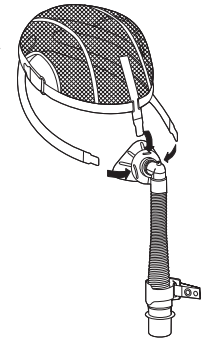
Step 1 The seams on the mesh of the Softcap Headgear face outward. Unhook the softcap headgear's tabs and thread them through the slots in the mask. Fasten the tabs onto the straps for the largest size possible.

Step 2 Hold the mask in place on the tip of your nose, pressing comfortably against your face, and slide the softcap headgear over your head. Adjust the upper side straps to bring the cushion close to your face. Adjust the center strap so that the cushion sits comfortably over your nose. The headgear and mask should fit snug, but not tight.

Step 3 Connect the circuit tubing to the mask swivel. Turn the CPAP or bi-level system on. Optional: Attach the stability clip to the headgear strap.

Step 4 Lie down and breathe normally through your nose, keeping your lips closed. Unhook the straps and gradually tighten them until the mask has minimal leaks and fits comfortably. Adjust the top straps first, making sure that they are above your ears. Adjust the bottom straps, making sure the headgear securely fits the back of your head. Readjust the strap tension if leaks occur as your position changes. **NOTE: Do not** overtighten the straps. Overtightening can cause leaks.

NOTE: The tubing can be worn upward (over the head) or downward as desired using either the Standard or the Softcap Headgear.



REMOVING THE MASK AND HEADGEAR

Because the entire headgear stretches, you should not need to unfasten the straps to remove the headgear. Simply slide the mask and headgear over your head, as you would a cap. If necessary, unfasten either of the bottom straps.

CLEANING INSTRUCTIONS

For Multi-Patient Use: Contact Respironics Customer Service at 1-800-345-6443 to obtain Mask Disinfecting Instructions (Order #1011138).

For Home Use: Clean the mask daily. Clean the headgear at least once each week or more often if needed.

Daily Cleaning

NOTE: It is not necessary to disconnect the headgear for daily use and cleaning.

Hand wash the mask in warm water with mild dishwashing detergent.

- **Do not** use bleach, alcohol, or cleaning solutions containing alcohol.
- **Do not** use cleaners containing conditioners or moisturizers.

Rinse thoroughly and air dry completely before use.

Inspect the mask and tubing for damage or wear; replace if necessary.

Weekly Cleaning

Hand or machine wash (gentle cycle) the headgear in warm water with standard laundry detergent.

- **Do not** use bleach, alcohol, or cleaning solutions containing alcohol.

Line dry or machine dry at the lowest heat setting.

Slight readjustments to the straps may be necessary.